

LAPAROSCOPIC CHOLECYSTECTOMY

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*"The surgical word for the 1990's is **laparoscopy**. Driven by the patient's desire for less pain, an extremely short recovery period (when no complications are present), a desire for sales by the medical-industrial complex, and efforts by surgeons to keep or enlarge their market share, laparoscopic techniques, mainly cholecystectomy, are a bull market.*

Accessories to this trend are anesthesiologists, who benefit from longer operating times as the new technique is learned; hospitals, whose operating rooms are filled; and lawyers, whose personal injury suits are more numerous. Third party payers thought they would benefit from shorter hospitalizations, but because asymptomatic or mildly symptomatic patients with gallstones now become surgical patients, the number of cholecystectomies and third party costs will probably increase."¹

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The community of general surgery within the United States experienced a remarkable revolution from approximately 1989 through 1992. During that time, across the nation, the fundamental intraoperative techniques employed in the performance of cholecystectomy, the intraabdominal procedure most frequently rendered by United States general surgeons, were completely revised. In essence, conventional open laparotomy with cholecystectomy, i.e., open cholecystectomy (OC), the recognized gold standard for the treatment of gallstone diseases, was replaced by laparoscopy-assisted cholecystectomy, i.e., laparoscopic cholecystectomy (LC).^{2,3}

LC was initially described as a surgical encore to a gynecologic procedure in France in 1987.^{4,5} The first reports from the United States derive from procedures performed in 1988.^{6,7} At the time of the NIH Consensus Development Panel on Gallstones and Laparoscopic Cholecystectomy in September 1992, approximately 80 percent of cholecystectomies in the United States were being performed laparoscopically.²

The procedure involves distending the abdominal cavity with carbon dioxide gas and performing several sharp incisions through the anterior abdominal wall that are utilized as ports to permit the intraabdominal introduction of laparoscopic viewing and surgical instruments. These provide the surgeon with visualization and access for surgical maneuvers. The surgeon views the procedure through a video screen with magnification available. The gallbladder and its surrounding vital structures are visualized, the cystic duct and artery are isolated and divided, and the gallbladder is dissected free of its liver bed and pulled through one of the anterior abdominal wall incisions. When successfully performed, in comparison with OC, LC significantly reduces patient pain, hospital stays and postoperative convalescence.^{2,8}

As is true of most revolutions, the relatively rapid adoption of LC in the United States engendered considerable controversy.^{1,5,9,10} Approximately 10 percent of this nation's population, more than 20 million people, suffer gallstones, and one million new cases are diagnosed annually. In 1991, nearly 600,000 patients underwent cholecystectomy. Gallstones are the most common and most costly digestive disease requiring hospitalization in the United States, and their related annual costs exceed five billion dollars.^{2,3}

At the time of the 1992 NIH Consensus Panel, approximately 15,000 surgeons had received some form of LC training. Often, this training was sponsored, in whole or in part, by instrument manufacturers. Unlike medications or medical devices, surgical procedures are not required by law to undergo pre-market testing to establish safety and efficacy. A national prospective controlled trial of LC was never undertaken. Now, it is generally conceded, none will be. Many doubt that patients could be recruited as volunteers, and some question whether such a study could be ethically undertaken.^{10,11} The prospective experiences with LC of

a number of groups and institutions have been published.^{8,12,13,14,15} Internal experience with conventional cholecystectomy or the established literature regarding OC served as historical controls.

It has been reasonably established that, in skilled hands, clinical outcomes with LC compare favorably to those with OC. A steep “learning curve” exists, however, during the adoption of and adaptation to laparoscopic techniques when the potential for major complications and dire patient outcomes, to include death, has been realized.^{8,16,17} Direct palpation is not possible. Exposure for visualization and examination can be frustrated and limited. True stereopsis is unavailable. The sentient cornerstones that have historically provided the foundation for skilled intraoperative surgical care within the abdomen are severely compromised.¹⁸

Professional organizations have suggested guidelines for the training of surgeons, their certification, and their clinical privileging for laparoscopic cholecystectomy.¹⁹ New York promulgated mandatory health department regulations after reports surfaced regarding significant complications, with a number of deaths, during the introduction of LC to that state.²⁰ One widely noted concern is the occurrence of major bile duct injuries with LC, especially those not detected during the procedure. Further, there are perforations and other sharp injuries to vessels and bowel during LC that are either unique to the surgery or rarely encountered with OC. Again, when these occur without detection, clinical outcomes may be dire.²¹

In recent years, the surgical literature has included a number of reported series of conventional, open cholecystectomies with either no mortality or mortality at an extremely low rate and limited to older patients with serious co-morbid diseases, most often when acute cardiovascular events occurred during surgery. Mortality experienced with laparoscopic cholecystectomy is increased during the learning phase and later declines to absolute rates consistent with prior OC studies. This remains, however, rather disconcerting because LC deaths occur in a younger population with intraoperative injuries to the bile ducts or other intraabdominal organs and not secondary to significant co-morbid disease with acute cardiac arrests in older patients.^{17,22,23,24,25}

THE PIAA SURVEY

The Physician Insurers Association of America (PIAA), as reviewed previously in this publication, was organized in 1977 as a national representative body of those medical liability insurance companies owned or directed by physicians.²⁶ PIAA maintains a Data Sharing Project regarding medical malpractice claims filed against member companies since 1985, and there are more than 100,000 malpractice claims that have been submitted to that project. The organization has also published specialized, focused reviews derived from subsets of that malpractice database.

In 1994, PIAA published a survey of malpractice claims filed with member insurers regarding all forms of laparoscopic surgery.²⁷ This study was undertaken in 1993, at the request of the organization’s membership, and 31 of 47 PIAA constituent companies agreed to participate.

Those insurers are identified in an appendix to the published study. They represent, from across the United States, a spectrum of the smallest to the largest PIAA insurers.

The survey was completed by September 1993. It should be noted that, from data in the complete PIAA malpractice database, on average, 22 months pass between the time of provision of clinical services and the receipt of a malpractice claim. Further, the average time from receipt of a claim to final closure is another six years, and there are claims not closed for 10 years. This study, unlike any other focused research published by PIAA, could not be a review of closed claims and must be interpreted accordingly. PIAA deems the results preliminary. Many survey forms forwarded to participating insurance companies, due to a lack

of complete legal discovery and other characteristics of malpractice claims when not closed, were returned lacking entries for all data requested.

The primary focus of the survey, given the nature of open claims, was an attempt to identify patient injuries (Table 1), along with certain demographic attributes of both providers and patients, that might be useful for loss prevention purposes.

With regard to all laparoscopic procedures, there were 615 claims reported in the PIAA survey, and they arose after the performance of 13 different kinds of surgery. The study concentrates upon the 331 claims (54 percent) that arose after the performance of laparoscopic cholecystectomy. Interestingly, the first LC related malpractice claim in the PIAA survey was filed in April 1989, rather early in the American experience with LC surgery. Among the remaining 284 laparoscopic surgery claims, the other 12 surgical procedures chiefly occurred during the provision of gynecologic services. Diagnostic gynecologic laparoscopy was the source of 50 percent of those claims (142 cases), and tubal ligation was the source of 50 percent of the remainder (71 cases).

For comparison purposes, the study organizers extracted data from 366 conventional open cholecystectomy procedures that had been the source of malpractice claims filed with the organization's general Data Sharing Project between 1985 and 1992. On average, the patients in the LC population were younger (43 years old) than those from the claims after OC surgery (46 years old). Further, the LC patients were more often female (84 percent) than in the OC cases (64 percent). Among the laparoscopic cholecystectomy claims, the provider specialty was general surgery more than 90 percent of the time (Table 2). Other specialties, however, were represented. There were three claims filed with regard to resident providers.

PIAA STUDY: LC INJURY		
N=347		
INJURY	NUMBER	
Common Bile Duct - Perforation, lacerations, punctures, leakage	197	
Hepatic Duct - Same injuries as above	45	
Bowel area - Same injuries as above	38	
Arteries & veins - Punctures, tears	32	
Fistula	8	
Equipment burns	7	
Retained gallstones	3	
Retained surgical foreign body	2	
Other	15	

TABLE 1

PIAA STUDY: LC PROVIDER SPECIALTY		
N=331		
SPECIALTY	NUMBER	PERCENT
General Surgery	304	91.8
Cardiovascular/Thoracic Surgery	12	3.6
Ob/Gyn	5	1.5
General/Family Practice	4	1.2
Resident	3	0.9
Colon-Rectal Surgery	1	0.3
Gastroenterology	1	0.3
Pediatrics	1	0.3

TABLE 2

The most frequent adverse clinical outcome for injured LC patients was undergoing a second operation. This commonly reflected the performance of a Roux-en-Y procedure to bypass a severe bile duct injury. It is noteworthy that in 243 of the LC claims (75 percent), the injury to the patient was not recognized at the time of initial surgery. The surgeon recognized the appearance of an injury in 85 cases and, most often, converted surgery to a conventional open cholecystectomy.

Employing an injury severity scale derived from the National Association of Insurance Commissioners, the PIAA study calculated a mean injury evaluation slightly more serious and severe for the comparison OC cases. In that group, 83 patients (22.7 percent) had died, while the mortality rate from the LC claims was 10.6 percent. The indemnity experience, however, does not conform to that data. When this study closed, in 1993, the majority of OC claims, 288 files (79 percent), were closed, and 92 cases (32 percent) had been

closed with payment. The average indemnity was \$96,800. In contrast, 94 LC claims (28 percent) had been closed, and 51 cases (54 percent) had been closed with payment. The average indemnity paid was \$136,000.

CASE AND COMMENT: INSTITUTIONAL LIABILITY

The patient was referred to the defendant surgeon on February 15, 1990, for a consultation regarding treatment of gallstones. The surgeon had participated in and was certified as having completed a laparoscopic cholecystectomy workshop on February 10, 1990. After concluding his evaluation of the patient, the surgeon recommended that she undergo laparoscopic cholecystectomy. On the next day, February 16, 1990, the surgeon asked the president of the defendant hospital to amend his surgical privileges to include the temporary privilege of performing laparoscopic cholecystectomy with the assistance of an experienced laparoscopist.

Laparoscopic cholecystectomy was performed on February 20, 1990. The patient is described as having experienced a complication of that procedure that resulted in significant hemorrhage and death. In time, a malpractice suit was filed against the hospital, the surgeon, and the assisting physician. Prior to trial, the defendant hospital argued that it should be granted summary judgement and dismissed from the litigation, contending that longstanding state law was inconsistent with imposing liability upon a hospital for the care of a private patient by an independent staff surgeon. Motion for summary judgement was denied by the trial court, denial of that motion was affirmed at the Georgia Court of Appeals, and certification to the state supreme court for further appeal was declined.²⁸

For purposes of the appellate opinion, it was considered true as alleged by the plaintiff, the patient's estate, that the assistant-proctor surgeon in this case was a specialist in gynecology who admitted that he was without any skill or experience in the performance of laparoscopic cholecystectomy. There was no evidence that he had ever performed the surgery.

Utilizing more recent and relevant precedent from the Supreme Court of Georgia and from authoritative cases in other jurisdictions, the appellate court determined that it was an obligation of all hospitals in the state to assume a direct and independent legal responsibility for every hospitalized patient and to take all reasonable steps necessary to insure that staff physicians were qualified for any clinical privileges granted. The court returned this case for trial with an expectation that, were facts proven as alleged, the hospital could be held liable for this patient's death due to negligent administration either in the granting of privileges to or the supervision of an independent medical staff member when performing laparoscopic cholecystectomy.

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Few judicial opinions from cases involving laparoscopic cholecystectomy have been reported in the on-line databases available to our office. As suggested by the PIAA study, this likely represents the somewhat characteristic "long tail" of malpractice disputes generally and may reflect specifically a prolongation of that time after the introduction of a novel form of treatment. When LC related malpractice cases eventually arrive in court, they will be subjected to lengthy deliberative opinions. No one today can presage those analyses, but the general categories of probable allegations are clear.²⁹

One allegation will be that the surgeon in question, due to limitations of training or skill or experience, should never have performed the procedure. This type of allegation, a double-edged claim, poses simultaneously the potential for imposing individual liability on the surgeon and institutional liability on the health care organization that permitted an incompetent staff member to perform the procedure. Every detail of the surgeon's laboratory experiences with this procedure, the specifics of the initial and ongoing supervision while

performing the surgery, the nature of the certification of competence, and the history of assisting others and being assisted in performing the procedure will be investigated, documented, and introduced into evidence. By necessity, the hospital's practices and procedures will be similarly scrutinized.

Another form of allegation will be that the surgery undertaken was, in fact, negligently performed. Evidence to support a contention of technical deficiency in the surgery as performed will be sought from the nature of the injury suffered, the findings at the time of later treatments, whether rendered by the initial provider or others, and the results of autopsy, where applicable. A striking medicolegal novelty could arise during LC related litigation, because many of the intraoperative maneuvers undertaken during laparoscopic cholecystectomy are videotaped. Those videotapes will be subpoenaed and critically analyzed. Usually, courts permit a weighty inference against the interests of any party who, charged with the responsibility of maintaining physical evidence such as a videotape, allows that evidence to be misplaced or lost or altered.

Lastly, allegations premised upon a lack of informed consent can be expected in LC malpractice cases. Disclosing to patients an adequate amount of information regarding the risks and benefits of a proposed therapy that is novel or under investigation presents serious challenges to all practitioners. Courts have generally voiced a desire that patients undergoing any medical procedure be adequately informed of the "material" risks, benefits, and alternatives.³⁰ The literature regarding laparoscopic cholecystectomy seems to establish, minimally, that the risks associated with the procedure's learning curve are undeniably material. Furthermore, the literature, on its face, already has proclaimed another form of surgical treatment a "gold standard" alternative, readily available and well-established across the nation.²³ Should "patient demand" be proffered as having forced the hand of surgical professionals into performing LC, more than two decades of developments in American civil law regarding consent to medical treatments clearly predict a resolute judicial response: *That better be **informed** patient demand!*

CONCLUSION

In 1989, McSherry reported the last installment of a 52-year consecutive registry of patients, from 1932 through 1984, who underwent surgery for nonmalignant biliary tract disease at a single medical institution, the New York Hospital-Cornell Medical Center.²³ The complete registry referenced 14,232 patients, and the 1989 report emphasized the previously unreported six-year experience from 1978 through 1984. The latter years of surgery, all conventional open cholecystectomies or related procedures, were contrasted with prior published reports.^{31,32,33} The article, referring to this surgery as the "gold standard" for the treatment of nonmalignant biliary tract disease, compares and contrasts the experience of patients from the registry at different times, especially with regard to the rate and the nature of complications and the rate and the causes of death.

When published, the author's clearly enunciated purpose was to contrast this experience with certain nonsurgical alternatives determinedly advocated at that time, namely, bile acid therapy, alone or in conjunction with extracorporeal shock-wave lithotripsy, and contact dissolution. In the opinion of McSherry, among the 30 deaths that occurred in the 2,386 patients surgically treated from 1978 through 1984, there was only one patient who was a potential candidate for bile acid therapy or lithotripsy, given the applicable criteria limiting their utilization. He remarked, "This study clearly illustrates the fallacy of attempting to compare two entirely different treatment modalities in two different patient groups in the absence of a prospective, randomized study. There is no validity to any statistical comparison of the risk of cholecystectomy with that of bile acid therapy alone or in combination with lithotripsy."²³

McSherry commented that all of the available nonsurgical techniques suffered from the serious consequence of leaving a diseased gallbladder in-situ and permitting the recurrence of gallstones. He concluded with the following statement: "The only real justification for the nonoperative solutions to gallstone disease is the infrequent but often devastating complication of intraoperative common bile duct injury. This complication still occurs despite advances in surgical training. The burden that it frequently imposes is a shortened life span frequented by repeat operations interspersed with bouts of cholangitis. If this disaster could be eliminated there would be no justification to seek alternatives to cholecystectomy."²³ Simple logic would appear to argue that this author, along with other leading American general surgeons in 1989, would have applied equivalent analytical criteria to any proffered **surgical** alternative to the established procedure. Simple logic, however, does not always control events.

No evidence yet exists that a deluge of liability claims and payments has followed the relatively rapid adoption of LC across the United States. The performance of standard open cholecystectomy historically has occasioned the most numerous malpractice claims filed against general surgeons after intraabdominal surgery.³⁴ A significant amount of time will need to pass before sufficient data is available to substantiate a conclusion that LC malpractice claims have not only replaced OC cases but disproportionately so, in frequency or severity or both. The metaphor of an inundation is not yet justified.

There are, however, distant rumblings, and there may well be reason to keep one's medicolegal foul weather gear at hand. The Association of Trial Lawyers of America has impaneled a "Laparoscopic Litigation Group" to serve as a national resource center and informational clearinghouse for plaintiff lawyers filing claims regarding this type of surgery. [Personal communication. Association of Trial Lawyers of America, Laparoscopic Litigation Group, T. Tsarouhas, Esq.] In 1992, Scott, *et al.*, reported a survey reviewing the 23 series previously published in the surgical literature regarding outcomes for 12,397 patients undergoing LC.¹⁶ The authors then estimated that more than 150,000 LC surgeries had been performed in the United States. Reports of experiences from academic centers or from academic centers in association with community providers may not accurately reflect the operative experiences of surgeons elsewhere. Others have suggested that medical referral centers have become increasingly more involved in the secondary treatment of patients who have experienced serious LC complications.²

Lawyers charged with the responsibility of defending physicians in malpractice cases involving invasive treatments take great comfort when that medical care is provided after having been proven scientifically "standard" in sound clinical trials. Similar to the reaction of physicians, those attorneys are granted considerable security when such evidence exists and supports either their client's providing a treatment or declining to do so.^{35,36,37} Legal arguments that the doctor's action was reasonable and prudent and knowledgeable can be persuasively evinced when the decision is so wisely substantiated. Highly invasive surgery that causes serious patient injuries can pose particular difficulties for the provider's legal representatives when a malpractice claim arises in the absence of sound clinical evidence supporting the procedure's safety and efficacy.

For centuries, our common law has construed the doctor-patient relationship as, at once, professional and fiducial. The interests of the patient, thereby, are legally paramount and granted both deference and protection by the courts. As the quotation that introduced this article suggests, there appear to have been a number of parties served and varied interests advanced during the revolutionary adoption of laparoscopic cholecystectomy in this country. As difficult as are predictions of legal events, the resilience of precedent in these regards makes clear the unfavorable judicial reaction should it be proven that the care, the health, or the safety of a patient was jeopardized when the treating physician or those legally associated with that physician served primarily, in fact, some other master.

REFERENCES

1. Braasch JW. Laparoscopic cholecystectomy and other procedures. Arch Surg. 1992; 127:887.
2. NIH Consensus Panel on Gallstones and Laparoscopic Cholecystectomy. Gallstones and laparoscopic chole-cystectomy. JAMA 1993; 269: 1018-1024.
3. Johnston DE, Karlan KM. Pathogenesis and treatment of gallstones. NEJM. 1993; 328:412-421.
4. Dubois F, *et al.* Celioscopic cholecystectomy: Preliminary report of 36 cases. Ann Surg. 1990; 211:60-62.
5. Dubois F, *et al.* Laparoscopic cholecystectomy: Historical perspective and personal experience. Surg Laparoscopy Endoscopy. 1991; 1:52-57.
6. Reddick EJ, Olsen DO. Laparoscopic laser cholecystectomy: A comparison with mini-lap cholecystectomy. Surg Endoscopy. 1989; 3: 131-133.
7. Gadacz TR, *et al.* Laparoscopic cholecystectomy. Surg Clin North Am. 1990; 70: 1249-1262.
8. The Southern Surgeons Club. A prospective analysis of 1,518 laparoscopic cholecystectomies. NEJM. 1991; 324: 1073-1078.
9. Perissat J, Vitale G. Laparoscopic cholecystectomy: gateway to the future. Am J Surg. 1991; 161: 408.
10. Nussbaum R, Fromm H. Laparoscopic cholecystectomy: A new procedure in need of further study. Gastroenterology. 1992; 102: 362-364.
11. Neugebauer E, *et al.* Conventional versus laparoscopic cholecystectomy and the randomized controlled trial. Br J Surg. 1991; 28: 1249-1262.
12. Zucker KA, *et al.* Laparoscopic guided surgery. Am J Surg. 1991; 161: 36-42.
13. Larson ML, *et al.* Multipractice analysis of laparoscopic cholecystectomy in 1,983 patients. Am J Surg. 1992; 163: 221-226.
14. Soper NJ, *et al.* Comparison of early postoperative results for laparoscopic versus standard open cholecystectomy. Surg Gyn Obstet. 1992; 174: 114-118.
15. Cappuccino H, *et al.* Laparoscopic cholecystectomy: 563 cases at a community hospital and a review of 12,201 cases in the literature. Surg Laparoscopy Endoscopy. 1994; 4: 213-221.
16. Scott TR, *et al.* Laparoscopic cholecystectomy: A review of 12,397 patients. Surg Laparoscopy Endoscopy. 1992; 2: 191-198.
17. Deziel DJ, *et al.* Complications of laparoscopic cholecystectomy: A national survey of 4,292 hospitals and an analysis of 77,604 cases. Am J Surg. 1993; 165: 9-13.
18. Gaster B. A piece of my mind: The learning curve. JAMA. 1993; 270: 1280.
19. Dent TL. Training, credentialling, and granting of clinical privileges for laparoscopic cholecystectomy. Am J Surg. 1991; 161: 399-403.

References continue on the next page.

REFERENCES, cont'd

20. Actman LK. Surgical injuries lead to new rules. New York Times. June 14, 1992, 1.
21. Wolfe Bm, *et al.* Laparoscopic cholecystectomy: A remarkable development. JAMA. 1991; 265: 1573-1574.
22. Pickelman J, Gonzalez RP. The improving results of cholecystectomy. Arch Surg. 1986; 121: 930-934.
23. McSherry CK. Cholecystectomy: The gold standard. Am J Surg. 1989; 158: 174-178.
24. Gilland TM, Traverso LW. Modern standards for comparison of cholecystectomy with alternate treatments for symptomatic cholelithiasis with emphasis on long-term relief of symptoms. Surg Gyn Obstet. 1990; 170: 39-44.
25. Morgenstern L, *et al.* Twelve hundred open cholecystectomies before the laparoscopic era: A standard for comparison. Arch Surg. 1992; 127: 400-403.
26. Connors PJ. The 1993 PIAA Medication Error Study: A summary. Legal Medicine Open File. 1994; 94-2: 13-16.
27. Physician Insurers Association of America. Laparoscopic Procedure Study. Washington, DC: Physician Insurers Association of America; May 1994.
28. *Candler v. Persaud*, 442 S.E.2d 775, 212 Ga. App. 762 (1994).
29. Hatlie MJ. Climbing the "learning curve": New techniques, emerging obligations. JAMA. 1993; 270: 1364-1365.
30. Mawn SV. Informed consent. Legal Medicine Open File. 1994; 94-2: 1-6.
31. Glenn F, Hays DM. The causes of death following biliary tract surgery for nonmalignant disease. Surg Gyn Obstet. 1952; 94: 283-296.
32. Glenn F, McSherry CK. Etiological factors in fatal complications following operations upon the biliary tract. Ann Surg. 1963; 157: 695-706.
33. McSherry CK, Glenn F. The incidence and causes of death following surgery for nonmalignant biliary tract disease. Ann Surg. 1980; 191: 271-275.
34. Physician Insurers Association of America. Data Sharing Project, Cycle 17 - June 1993. Washington, DC: Physician Insurers Association of America; June 1993.
35. Cryotherapy for Retinopathy of Prematurity Group. Multicenter trial of cryotherapy for retinopathy of prematurity: One year outcome: Structure and function. Arch Ophthalmology. 1990; 108: 1408-1416.
36. Sergot RC, *et al.* Optic nerve decompression may improve the progressive form of nonarteritic ischemic neuropathy. Arch Ophthalmology. 1989; 107: 1743-1754.
37. The Ischemic Optic Neuropathy Decompression Trial Research Group. Optic nerve decompression for nonarteritic ischemic optic neuropathy (NAION) is not effective and may be harmful: Results of the Ischemic Optic Neuropathy Decompression Trial (IONDI). JAMA. 1995; 273: 625-632.